REMARKS

The Examiner contends that the application contains two inventions which are not so linked as to form a single general inventive concept under PCT rule 13.1, and has required restriction. The Examiner has defined the inventions as follows:

Group I, claims 1-5 and 8-12, drawn to a method of using a compound of an interleukin receptor antagonist (IL-1Ra) for the treatment of prophylaxis of type 2 diabetes in a mammal; and

Group II, claims 6-7 and 13-14, drawn to a method of using a compound of a pyrrolinidedithiocarbamate (PDTC) for the treatment or prophylaxis of type 2 diabetes in a mammal.

The Examiner alleges that the claims of Groups I and II do not relate to a single general inventive concept under PCT rule 13.1 because, under PCT rule 13.2, they lack a corresponding special technical feature (Office Action, page 2). In particular, the Examiner contends that claim 1 is directed to a composition comprising interleukin receptor antagonist (IL-1Ra) for the treatment or the prophylaxis of type 2 diabetes in a mammal. The Examiner asserts that Giannoukakis et al. (1999) teaches IL-1Ra for the prevention and treatment of insulitis and the consequent pathogenesis of diabetes. The Examiner contends that, because the prior art meets the limitations disclosed in claim 1, the corresponding technical feature is not special. Applicants respectfully traverse.

Applicants submit that Giannoukakis in fact fails to teach the limitations of claim 1. In particular, Giannoukakis teaches that adenoviral gene delivery of the cDNA encoding the IL-1Ra protein to cultured Islets of Langerhans cells blocks the macrophage-derived interleukin-1β function of eliciting auto reactive T-cells to target and destroy β-cells in Islets of Langerhans in type 1 diabetes. In contrast, Applicant's claim 1 is directed toward the prophylaxis or treatment of type 2 diabetes based on the use of IL-1Ra in mammals.

It is well known that type 1 and type 2 diabetes are distinct. Type 1 diabetes is caused by the *lack* of insulin production due to insulitis, which is known to be the disease condition resulting from the destruction of insulin producing cells within the Islets of Langerhans by the infiltration of auto-reactive T-cells. In contrast, type 2 diabetes is caused by the *resistance* to insulin, and insulin is still produced by individuals suffering from type 2 diabetes.

It follows that, in contrast to the Examiner's assertion, the claimed invention in fact has a special technical feature not disclosed by the prior art. Applicants therefore submit that restriction is improper, and respectfully request rejoinder of the claims of Groups I and II for examination in a single application.

Applicants also call the Examiner's attention to the fact no unity of invention objection was raised during the international phase of this application, which applied the unity of invention standard of PCT Rule 13. An international application that complies with those unity of invention requirements must then be accepted by all of the designated and elected offices, including the USPTO, since Article 27(1) of the Patent Cooperation Treaty does not permit any national law or national office to require compliance with different regulations relating to the contents of the international application.

The U.S. application must therefore be examined for Unity of Invention consistent with the Patent Cooperation Treaty, not just by giving verbal assent to the unity of invention standard by mere reference to the PCT Rule, but rather an actual application of the standard. See *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 231 USPQ 590 (E.D. VA 1986). In this case, proper application of the unity of invention standard means that the application of PCT Rule 13 by the USPTO should be consistent with the application by the PCT Examiner of the same rule for the same subject matter. This means that the Examiner's restriction requirement is improper, and that all of the claims in the application should be searched and examined together.

In order to be fully compliant with the Restriction Requirement, Applicants elect, with traverse, to pursue the claims of Group I.

Applicants also point out that the paragraph bridging pages 2-3 of the Office Action does not appear to be applicable to the present application. There, the Examiner states that the claims of Groups I-IV do not relate to a single general inventive concept because they lack the same or corresponding technical feature. The Examiner, however, has segregated the claims of the present invention into two groups, not four. In addition, all of the claims of the present application are accounted for in Groups I and II, which further indicates that this paragraph was mistakenly included in the present Restriction Requirement.

Applicants respectfully request early action on this application, and allowance of all the claims, which define patentable subject matter.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson, Registration No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

#47,604

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